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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,124	04/09/2001	Zhong-Min Wei	21829/101 (EBC-008)	2301

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EXAMINER	
KUBELIK, ANNE R	
ART UNIT	PAPER NUMBER
1638	

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14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/829,124	WEI ET AL.	
	Examin r	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-18,90 and 91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-4, 6-18, 90, 91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 5 and 19-89 have been cancelled, claims 1-4, 6, 8, 11, 13, 16 and 18 have been amended, and claims 90-91 have been added, as requested in Paper No. 11, filed 10 March 2003. Claims 1-4, 6-18 and 90-91 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. Claims 1-2, 6-18 and 90-91 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 5 September 2002, as applied to claims 1-18. Applicant's arguments and the Declaration of Zhong-Min Wei, both filed 10 March 2003, have been fully considered but they are not persuasive.

Applicant urges that they have identified a single species of *hreX* and have demonstrated by Southern hybridization that *hreX* is widespread among Xanthomonas pathogens. Applicant also urges that HreX shares properties with other hypersensitive response elicitors. Applicant reiterates the Declaration of Dr. Zhong-Min Wei, filed with the response, and both will be summarized together (all cited references were sent with the Declaration): Hypersensitive response elicitor proteins are an art-recognized class of proteins and share the unique ability to cause distinct plant responses. Gopalan et al (1996, Plant Dis. 80:604-610) teaches that the hypersensitive response results from an incompatible interaction between plant pathogens and

non-host plants and this reaction is distinct from a compatible interaction. Gopalan also teaches that hypersensitive response elicitor proteins from one genus are often homologous to elicitors of a different species and genus. Bauer et al (1995, MPMI 8:484-491), Cui et al (1996, MPMI 9:565-573), Ahmad et al (1996, 8th Int'l Cong. Molec. Plant Microbe Inter.), and Preston et al (1995, MPMI 8:717-732) teach that a nucleic acid encoding a hypersensitive response elicitor protein from one bacterial species was used to isolate a nucleic acid encoding a hypersensitive response elicitor protein from the same genus. Bonas (1994, Current Topics in Microbiol. Immunol. 192:79-98), Alfano et al (1997, J. Bacteriol. 179:5655-5662), and Swanson et al (1999, Phytopath. 90:S75) teach that genes encoding hypersensitive response elicitors are arranged in gene clusters. Bogdanove et al (1996, Molec. Microbiol. 20:681-683) teach that most hypersensitive response elicitors are secreted through the type III secretion system. Bonas (*op cit*) and Wei et al (2000, MPMI 13:1251-1262) teach that the genes are regulated by environmental factors. Bonas (*op cit*), Bonas (1994, Trends Microbiol. 2:1-2), Alfano (*op cit*), Gopalan (*op cit*), and Fan et al (WO 01/98501) teach that hypersensitive response elicitor proteins share common characteristics and structure (Declaration, paragraphs 4-16 and response pg 4-7).

This is not found persuasive because hybridization under unspecified conditions does not describe DNA molecules that encode hypersensitive response elicitors; there is no demonstration that any of the hybridizing DNAs encode such proteins. The specification does not teach the structural features of such nucleic acids.

Applicant urges that given the above, one of ordinary skill in the art would understand that Applicant were in possession of SEQ ID NO:1 and of the nucleic acids identified in the Southern hybridization (response pg 7).

This is not found persuasive because Southern hybridization of genomic DNA is not the same thing as possession in the form of cloning an isolated DNA.

Furthermore, as amended, the claimed nucleic acid does not encode a protein with any specified function or any protein at all. Thus, written description is lacking for the claimed nucleic acid.

4. Claims 1-2, 6-18 and 90-91 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids encoding a hypersensitive response elicitor of SEQ ID NO:2, and plants transformed with that nucleic acid, does not reasonably provide enablement for any nucleic acid that hybridizes to SEQ ID NO:1, plants transformed with those nucleic acids and methods of imparting disease resistance in plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 5 September 2002, as applied to claims 1-18. Applicant's arguments and the Declaration of Zhong-Min Wei, both filed 10 March 2003, have been fully considered but they are not persuasive.

Applicant urges that the specification provides sufficient detail for one of ordinary skill in the art to determine if a given DNA molecule hybridizes to SEQ ID NO:1 and encodes an hypersensitive response elicitor. Applicant urges that Ausubel et al (1998, Current Protocols in Molecular Biology, Vol 1, pg 6.3.5-6 and 6.4.3-9) teaches what one of ordinary skill in the art would know with respect to hybridization time and wash conditions. Applicant urges that as further evidence that one of ordinary skill in the art would understand that standard hybridization times should be used in the Southern hybridization, Applicant notes that the 65 hr hybridization time and TMAC used in Example 12 because non-standard conditions were required due to the

high GC content of the probe, requiring departure from the recommendations of Ausubel et al. Applicant urges that in example 17, standard hybridization conditions were used, and thus they did not need to be specified (response pg 7-8).

This is not found persuasive because knowledge of hybridization and wash salt concentrations, temperatures and times are required to replicate the isolation of the claimed nucleic acid. For example, Ausbel states that different times are used depending on the "complexity" of the probe and the target DNA (pg 6.3.6, right column, paragraph 2).

Applicant urges that Given Applicant's identification of *hreX* in *Xanthomonas campestris* pv *pelargonii*, on of ordinary skill in the art would have expected homologs to be present throughout the *Xanthomonas* genus. Applicant summarizes the Declaration of Zhong-Min Wei to say that hypersensitive response elicitor homologs were found in *Erwinia* and *Pseudomonas* species, and example 17 of the instant specification teaches that such homologs are present in other *Xanthomonas* species. Applicant urges that one of ordinary skill in the art would be able to isolate the encoding DNA from these species and be able to determine whether the encoded protein elicits a hypersensitive response (response pg 8-9).

This is not found persuasive because it is the job of the Applicant to teach that the DNAs actually do encode hypersensitive response elicitors and to teach the sequence of those nucleic acids. Making and analyzing all the claimed nucleic acids, without further guidance would require undue experimentation.

Applicant urges that the specification does enable claims 12-18 because it describes the materials and techniques for making transgenic plants. Applicant reiterates the Declaration of Dr. Zhong-Min Wei, filed with the response, and both will be summarized together: Transgenic expression of hrpN in plants results in enhanced growth, and disease and stress resistance;

because HreX is a member of the art-recognized class of hypersensitive response elicitors, expression of HreX in plants would be expected to have the same effect. The Declaration presents data showing that topical application of HreX induced resistance to diseases caused by other pathogens, enhanced plant growth and induced plant stress resistance. Applicant also urges that Rugang et al (1999, Science in China 42:96-101) teach that both constitutive and inducible expression of hrpN in plants confers disease resistance without killing the plants (response pg 9-10 and Declaration, paragraphs 18-48).

This part of Applicant's arguments is found persuasive. However, neither the specification nor Rugang et al provide evidence that plants transformed with any nucleic acid that hybridizes to SEQ ID NO:1 would confer disease resistance on plants. Furthermore, the specification does not demonstrate that a cutting from a plant transformed with SEQ ID NO:1 is more desiccation-resistant than a cutting from a non-transformed plant.

Applicant urges that the Declaration presents data showing that topical application and transgenic expression of hypersensitive response elicitor proteins induced resistance to diseases caused by other pathogens, enhanced plant growth and induced plant stress resistance; thus one of ordinary skill in the art would have expected transgenic expression of other hypersensitive response elicitors to have the same effect (response pg 10-11).

This is not found persuasive because not all nucleic acids that hybridize to SEQ ID NO:1 will encode a hypersensitive response elicitor, and the claims do not require that they do.

5. Claims 1-4, 6-18 and 90-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The

rejection is modified from the rejection set forth in the Office action mailed 5 September 2002, as applied to claims 2-6, 8, 11 and 18, due to amendment of the claims. Applicant's arguments filed 10 March 2003 have been fully considered but they are not persuasive.

Applicant urges that the claims have been amended (response pg 11). This is not found persuasive because the following rejections are new, due to amendment of the claims:

Claim 1 is indefinite for its recitation of "for an effective amount of time" in lines 5 and 7, and claim 2 is indefinite for the phrase in line 5. It is unclear what the time is effective for - to ensure only the claimed nucleic acid hybridizes and no other? To ensure the claimed nucleic acid hybridizes and is not washed off? How does one of skill in the art know the metes and bounds of the claimed nucleic acid?

Claim 3 is indefinite in its recitation of "the amino acid of SEQ ID NO:2". As written, the claims are drawn to a DNA molecule that encodes a protein that comprises one amino acid of SEQ ID NO:2. If this is not what Applicant intended, it is suggested that "the amino acid of" be deleted or that --sequence-- be inserted before "of". Note that this is a modification of the rejection made in the prior office action, made due to amendment.

6. Claims 1-4, 6-18 and 90-91 are free of the prior art, given the failure of the prior art to teach or suggest an isolated nucleic acid encoding SEQ ID NO:2.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
May 7, 2003

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